

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **28 OCTOBER 2004 (28.10.2004)**

Applicant's or agent's file reference
PCTA9407-11

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2004/001891

International filing date (day/month/year)

27 JULY 2004 (27.07.2004)

Priority date(day/month/year)

06 AUGUST 2003 (06.08.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 38/18

Applicant

CJ Corp. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/001891

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/001891

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations :

Claims 1-6 of this invention relate to a formulation of albumin-freee EPO comprising hydroxyethyl starch or hydroxyethyl starch and amino acids

The following document have been considered for the purpose of this report:

D1= US 6,586,573 B1, Jul. 1, 2003

D2= Cryobiology, 2002, Vol. 45, No. 2, pp. 153-166.

1. Novelty

Claims 1-6 of this invention relate to a formulation of albumin-freee EPO comprising hydroxyethyl starch or hydroxyethyl starch and amino acids.

Document D1, which has been published prior to the filing date of the present application, discloses a formulation of albumin-freee Factor VIII comprising hydroxyethyl starch or hydroxyethyl starch and amino acids, which is different from those of this invention in terms of protein of interest for formulation. Therefore, the subject matter of claim 1-6 is considered to be novel [PCT Article 33(2)]

2. Inventive Step

The object of this invention and D1 have the same object of not containing albumin as a stabilizing agent for protein formulation. Also, the technical composition of this invention is similar to those of D1 such as protein of interest, amino acids and 0.1-10% hydroxyethyl starch compared to 2-6% in D1. But D1 utilized hydroxyethyl starch as a bulking agent, whereas this invention utilized it as a stabilizing agent. It has been known in the prior art that hydroxyethyl starch has stabilizing effect for freezing the protein without losing the activity, as described in D2. Thus it is not surprising selecting hydroxyethyl starch as stabilizer for EPO. But it have to be noted that the stabilizer and the resulting effect could be varied among the proteins according to physical and biochemical properties of proteins to be formulated. Thus, the effort to select stabilizer and to determine the stabilizing effect of hydroxyethyl starch should be appreciated as a surprising technical effect.

Therefore the subject matter of claims 1-6 is considered to involve an inventive step within the meaning of Article 33(3) PCT.

3. Industrial applicability

The subject matter of claims 1-6 is considered to be industrially applicable. [PCT Article 33(4)]